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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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02/27/2006

Daphne Atlas

29287

9326

67801

7590

01/22/2009

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,766	Applicant(s) ATLAS ET AL.	
	Examiner MEGHAN FINN	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Amendment filed September 25, 2008 has been received and entered into present application. Claims 8-9 and 13-19 were canceled and claims 2, 7, and 10 were amended by applicant. Claims 4-6 and 10-12 remain withdrawn for pertaining to the non-elected invention, and thus claims 1-3 and 7 are pending.

Applicants' arguments, filed September 25, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant has argued that claims 4-6 and 10-12 should be examined as they are directed to ester compounds which are pro-drug compounds of the elected compound J. This argument is not found persuasive, as these prodrugs that the claims pertain to are compounds A-H, which were included in the original election of species and applicant chose to not elect the prodrug. Furthermore, a search for N-acetyl cysteine amide (the elected species, compound J) would not be expected to uncover prior art that related to N-acetyl-cysteine-ethyl-ester (compound A, the prodrug of compound J). This argument was carefully considered but was not found persuasive and claims 4-6 and 10-12 remain withdrawn for pertaining to the non-elected invention.

Claim Rejections - 35 USC § 112 (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended claims 2 and 7 to claim compound J "or an ester pro-drug thereof". Applicant has only shown compound A as a pro-drug of compound J yet the claims encompass any compound which has an ester-moiety and functions as a prodrug of compound J and that encompasses far more compounds than applicant has shown or provided direction towards what compounds would be considered to be a pro-drug of compound J. Thus one of skill in the art at the time of the invention would not be able to determine what compounds are encompassed by applicant's claims 2 and 7 and they lack written description of the invention.

This is a new rejection necessitated by the amendment to claims 2 and 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1614

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of multiple sclerosis with compound J, does not reasonably provide enablement for treatment of multiple sclerosis with the other compounds or prodrugs claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the previous rejection mailed March 26, 2008, claims 1-3 and 7 were rejected for lack of enablement, the reasons of which are herein incorporated by reference. Applicant has argued that their specification does allow one of skill in the art to use the invention as claimed, and has argued the examiner's position conclusory and misplaced in law and science and that the examiner requires a mechanism of action for enablement. That was never the claim, intention, or result of the previous action, and the examiner apologizes if the applicant misinterpreted the basis of the previous rejection. Applicant has however, successfully alerted the examiner to the fact that the experimental autoimmune encephalomyelitis (EAE) test of example 11 is a standard animal model for MS. In light of that it appears that applicant is enabled for treatment of MS with compound J. However, even for claims 2 and 7 which are limited to compound J "or an ester-prodrug thereof" applicant has not shown what constitutes a pro-drug other than the one example of compound A and while the concept of pro-drugs is well known the practicality of developing and discovering compounds which are effective prodrugs is not that easy and with the little guidance given in the specification, it would

Art Unit: 1614

not enable one of skill in the art the time of the invention to use other ester-prodrugs for the treatment of multiple sclerosis.

In claims 1 and 3, applicant is not limited to compound J or any specific set of compounds. The claims read upon any compound with anti-oxidant properties which have a chemical make-up for permitting said compound to accumulate within the cytoplasm of cells. These claims encompass a wide range of compound which applicant has provided no direction towards and one of skill in the art would not be able to use a random antioxidant which fits the properties of claim 1 for treatment of multiple sclerosis only given in the information in the specification which is directed towards a specific type of compound.

This argument is not deemed persuasive and thus the rejection of claims 1-3 and 7 is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1614

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas et al. (WO 98/29375) in view of Passi et al. (US 6,303,139), each already of record, for the reasons set forth at page 7 of previous office action dated March 26, 2008, of which reasons are herein incorporated by reference.

Applicant has amended claims 2 and 7 to include ester pro-drugs of the elected compound J, however all the claims still read upon a method of treating multiple sclerosis with N-acetyl cysteine amide (compound J), which was previously rejected in the office action mailed March 26, 2008. The applicant has argued that a prima facie case of obviousness was not established previously, because rejections cannot be based on conclusory statements but must include articulated reasoning with rational underpinning to support the legal conclusion of obviousness. The examiner apologizes if applicant feels that the explanation in the previous office action was not clear enough to support the conclusion of obviousness, because they were supported by rationale and articulated reasoning. In an effort to provide clarity, Atlas et al. teaches compound J for treating oxidative stress (page 7, lines 25-35). Passi et al. teaches that oxidative stress is significantly involved in the pathogenesis of multiple sclerosis (abstract). Atlas et al. has made it clear to one of ordinary skill in the art that compound J would be a good treatment for oxidative stress, and one of ordinary skill in the art would be

Art Unit: 1614

motivated to look at other diseases in which oxidative stress is known to play an important role in order to expand the effectiveness of a treatment for oxidative stress. It is common in the art to take a treatment for some process in the body and look to see what other conditions might benefit from such a treatment. Passi et al. teaches that oxidative stress plays an important role in multiple sclerosis; this would lead one of ordinary skill in the art at the time of the invention to believe that the treatment of Atlas et al. could be used, with a reasonable expectation of success, for treatment of multiple sclerosis. A reasonable expectation of success being that the compound J is expected to reduce oxidative stress (taught by Atlas et al.) and a reduction of oxidative stress will be beneficial to a patient with multiple sclerosis as suggested by Passi et al. Applicant's argument that there would be no reasonable expectation of success because the antioxidants used in Passi et al. are structurally distinct from compound J is not found to be persuasive because it is the fact that compound J is known to have a good properties of reducing oxidative stress specifically that would make it a good candidate over those taught in Passi et al. The examiner never indicated that any anti-oxidant would work in this case; it was the specific teaching of Atlas et al. that compound J is useful for reducing oxidative stress that would make it useful in the method of Passi et al. This argument is not deemed persuasive and thus the rejection of claims 1-3 and 7 is **maintained**.

Conclusion

Rejection of claims 1-3 and 7 is deemed proper and is **maintained**.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 1614

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614